

REMARKS/ARGUMENTS

Status of the Claims

Claims 39-41, 65-68, and 71-74 are pending in the application. There are no current amendments to the claims of this patent application. There is no new matter added.

35 U.S.C. 102(e) rejections by Schmaltz et al. (U.S. 6,050,996)

Examiner has rejected claims 39, 65, 67, 71, and 73 under 35 U.S.C. 102(e) as being anticipated by Schmaltz et al. (U.S. 6,050,996). Examiner makes no explicit argument regarding claims 39 and 71 being anticipated by Schmaltz. Therefore, Applicant assumes that Examiner's 3rd paragraph beginning "In figure 1, Schmaltz et al. discloses an apparatus for bonding soft biological tissue . . ." was meant to apply to claims 39 and 71.

Applicant argues that Claims 39, 65 and 71 are not anticipated by Schmaltz because the adjustable stop member of claim 39 and the stop means of claim 71 are inherently different than that which is described in Schmaltz. Claim 39 describes an

adjustable stop member that limits the extent to which the forceps may be deformed, the stop member being adjustable to accommodate the bonding of tissues of varying thickness to provide tissue welding that forms a weld to reconnect the tissue.

Claim 65 is dependent on claim 39 and further describes forceps that have "two arms, and the adjustable stop member is positioned between the two arms of the forceps." Claim 71 describes an apparatus that has a "stop means for selectively limiting the extent to which the forceps may be deformed to provide tissue welding that forms a weld to reconnect the tissue."

As per this application's Specification, the adjustable stop means of claims 39 and 65 and the stop means of claim 71 are intended to allow the user to set the desired force of compression for a given tissue. In addition, the adjustable stop member and stop means prevent the user from exerting too much force on the tissue by resisting any increased pressure from the surgeon's fingers. "Further increase in pressure by the surgeon's fingers will not change the compression force applied by the electrodes." See Specification at paragraph 121.

Schmaltz (6,050,996) discloses a system of “interlocking ratchets designed to hold a constant closure force between the seal surfaces.” *See* Schmaltz (6,050,996) Abstract. Schmaltz discloses that an interlocking ratchet between the handles is required so that the apparatus can be clamped and locked in place. However, where as Schmaltz’s invention allows the ratchets to move past each other to increase the clamping pressure and allows the increased clamping pressure to be transferred to the flange of the incision, the Applicant’s stopping means resists clamping pressure such that it prevents exerting too much pressure. Therefore, the Schmaltz prior art is inherently different from the claimed invention.

Schmaltz additionally teaches against the current invention by arguing that such a design will yield a less predictable surgical outcome because the surgeon must constantly squeeze the handles of the device. However, Applicant recognizes the benefits of preventing the application of too much force on the incision. Too much pressure applied to the flange of the incision can result in considerable volumetric deformation of tissue in the bonding zone such that it increases the time required to heal the tissue after bonding. *See* Application at paragraph 35.

Because the Schmaltz prior art is inherently different from the current invention, teaches away from the current invention, and fails to recognize the benefits of the current invention, claims 39, 65, and 71 should be allowed over the claimed prior art, and Application requests that Examiner withdraw the 102(e) rejections to claims 39, 65, and 71 that rely on Schmaltz.

Examiner rejected claims 67 and 73 of the claimed invention as being anticipated by Schmaltz et al. (6,050,996) because Examiner understood that the ridges illustrated in Figure 1 of Schmaltz were to be one or more spacers. Although the system of interlocking ratchets allows for functions similar to those of the spacers, as disclosed by the claimed invention, the performance of the two is substantially different such that the former should not anticipate the latter. Both the ratchets and the spacers define the length of the gap between the two electrodes and the resultant force to be applied to the flange; however, the ratchets fail to anticipate the spacers and should not be understood as such because the ratchets lack the ability to prevent too much force from being applied to the

flanges of the incision, which can result in an increased risk of volumetric deformation and increased healing time as explained above. Because of the Schmaltz prior art's failure to safeguard against the dangers of exerting too much pressure on the incision, Applicant requests that Examiner withdraw the 102(e) rejections to claims 67 and 73 that rely on Schmaltz.

35 U.S.C. 102(e) rejections by Buysse et al. (U.S. 5,776,130)

Examiner rejected claims 39 and 71 under 35 U.S.C. 102(e) as being anticipated by Buysse et al. because Examiner argues that Buysse discloses an "adjustable stop member (22) that limits the extent to which the forceps may be deformed, the stop member being adjustable to accommodate the bonding of tissues of carrying thicknesses to provide tissue welding that forms a weld to reconnect the tissue." However, the mechanisms for applying pressure to the area to be bound are substantially different, and the Buysse prior art does not anticipate the current application. The Buysse patent discloses a lost motion connector to "transfer user manipulation of the actuator to the end effectors and for *maintaining predetermined clamping force applications...*" (emphasis added). The DETAILED DESCRIPTION OF THE INVENTION further discloses that the lost motion connector allows for "different levels of compression, i.e. no force, partial compression, and full compression" and is achieved by any acceptable "form of stepped latching arrangement that would hold the actuator 15 in a preset position."

Again, the disclosed adjustable stop member of claim 39 and stop means for selectively limiting the extent to which the forceps may be deformed of claim 71 are exceptionally different from and not anticipated by the Buysse patent. As detailed above, the current patent application discloses an apparatus that protects against a surgeon's excessive application of force. In the current application, when the stop member is adjusted to provide a predetermined distance between the electrodes, the electrodes cannot be forced closer to each other than the desired predetermined setting. "Further deformation of the arms [such as to exert too much pressure on the flange of the incision] under the pressure from the surgeon's fingers is limited by the lug and opposed arm coming in contact. ... Further increases of pressure by the surgeon's fingers will not change the compression force applied by the electrodes." Applicant's Specification

paragraphs 120-1. The current invention was designed in this way so as to decrease healing time and tissue scarring. The Buysse prior art provides a stepped latching arrangement with multiple stepped latching positions which maintain a minimum pressure on the flange, but will not prevent the surgeon from applying too much pressure to the flange. However, under the current invention, the surgeon may squeeze the forceps as hard as she desires without the fear of exerting too much pressure and exposing the patient to the described risks.

Because of the above arguments and differences, Applicant requests that the Examiner withdraw the 102(e) rejections to claims 39 and 71 that rely on Buysse.

35 U.S.C. 103(a) rejections by Schmaltz et al. (U.S. 6,050,996)

The Examiner rejected claims 40, 41, 66, and 72 as being obvious in light of Schmaltz et al. in view of the common knowledge known by one skilled in the art because Schmaltz teaches all of the limitations of the claims except the electrodes being made of a metal with a high heat conductivity, the electrodes being dimensioned to have a volume that is at least 5 times that of the tissue portion volume, and the lug being replaceable, which, as the Examiner argues, were all obvious to one skilled in the art at the time of invention. The Applicant respectfully disagrees and traverses the Examiner's rejections.

With regard to claim 40, the Examiner conclusively states that it has been held that discovering the optimum dimension involves only routine skill in the art. "The nonobviousness requirement extends the field of unpatentable material beyond that which is known to the public under § 102, to include that which could readily be deduced from publicly available material by a person of ordinary skill in the pertinent field of endeavor." *Bonita Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150, 109 S. Ct. 971, 977, 103 L. Ed. 2d 118, 134 (1989). At the time of the invention, it could not have been possible to deduce the optimum dimension of the electrode from the Schmaltz prior art. Nowhere in Schmaltz do the inventors discuss the effects of insufficient volume, such as the bonding starting at the electrode/tissue interface as opposed to the tissue/tissue interface. Such incorrect bonding location results in overheating of the electrode/tissue interface, which increases sticking of the electrode to the tissue and increases the length

of healing time needed. The volume is important, as disclosed in the specification, because the volume of an object defines its heat capacity and, thus, its ability to function effectively as a heat sink and withstand several successive bonding cycles without overheating. Given that none of the aforementioned was even contemplated in the prior art, Schmaltz does not render the current application obvious. Thus, the Applicant respectfully requests that the Examiner withdraw the 103(a) rejection to claim 40.

With regard to claim 41, the Examiner conclusively states that it has been held that one with the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use is a matter of obvious design choice. Applicant respectfully asserts that this is an overly broad interpretation of obviousness, particularly in light of the complexity of the field of materials sciences. For example, it is an obvious design choice that one would not make a passenger airplane from lead. But given the state of the art at the time of the invention, choosing between two suitable electrode materials (e.g. copper and stainless steel) is not an obvious design choice because it requires scientific reasoning and experimentation. The state of the art at the time of the invention was developing, and such small but important differences were not yet being discussed. Out of the three patents currently cited as prior art, not one mentions temperature of the electrode or of the flange along the incision, or the heat conductivity of the electrode, or the effects of over-heating the flange about the incision. It would be impossible for one skilled in the relevant art at the time of the invention to readily deduce such improvements from the publicly available material; thus, the Applicant respectfully requests that the Examiner withdraw the 103(a) rejection to claim 41.

With regard to claims 66 and 72, the Examiner rejected both based on official notice that the artisan would consider the stop member disclosed by Schmaltz et al. to be a lug, which would render obvious the lug because replaceability involves only routine skill in the art. Applicant respectfully submits that Examiner's interpretation of both the Schmaltz prior art and the current application is incorrect. The Schmaltz prior art discloses a system of interlocking ratchets with several positions. "The strain energy that is stored in the shank provides a constant closure force between the electrodes." See Schmaltz et al. Detailed Description of the Invention. The Schmaltz prior art continues:

“A design without a ratchet requires the surgeon to hold the electrodes together by applying a constant squeeze to the handles.” Schmaltz discloses that experimentation indicates the superiority of the Schmaltz disclosure; however, the Applicant disagreed and therefore designed the current invention accordingly. The current application clearly discloses a lug that prevents excessive pressure from being exerted on the flange of the incision, as described above, in order to decrease the risks of tissue scarring and increased healing time.

In addition, the Applicant respectfully submits that one skilled in the relevant art would not consider the stop member disclosed by Schmaltz et al. to be a lug. Schmaltz specifically describes the stop member as being a ratchet system, which would be interpreted by one with skill in the art as Schmaltz disclosed in the claims, description, and drawings: a system of ratchets that interlock in order to hold the members that it separates in place. However, such a system of interlocking ratchets does not prevent the further compression of the members; it only prevents the separation of the members. Applicant directs Examiner to look at the device described as a hemostat, which traditionally uses the interlocking ratchet system that is disclosed in Schmaltz, as can be seen at http://www.tedpella.com/dissect_html/53096.htm as accessed December 19, 2005 and included as Appendix A. The lug, as disclosed by the Applicant, both defines a separation of the electrodes and prevents too much pressure from being exerted on the flange of the incision as can be seen in Figure 16 as lug 104. The prior art interlocking ratchet system and the current application's lug stopping member are sufficiently different such that the 103(a) rejections to claims 66 and 72 should be withdrawn.

35 U.S.C. 103(a) rejections by Schmaltz et al. (U.S. 6,050,996) in view of Choudhury et al. (U.S. 5,219,354)

Examiner rejected claims 68 and 74 as being obvious in light of Schmaltz et al. in view of Choudhury (U.S. 5,219,354) because the Examiner argues that Schmaltz teaches all of the limitations of the claims except for the adjustable stop member comprising an adjustable knob, which Examiner claims is disclosed in Choudury. However, Applicant respectfully disagrees with Examiner's interpretation of the prior art and argues that Examiner's interpretation is incorrect. As discussed above, Schmaltz teaches an

interlocking ratchet system as a stopping member. The Schmaltz stopping member does not prevent excess pressure from being applied to the flanges of the incision but only sets the distance between the electrodes. There is still risk of scarring and increased healing time associated with an overexertion of pressure by the user. Choudry teaches a mechanism similar to the Schmaltz interlocking ratchet system that comprises a “knob” that interlocks with a series of ratchets, which decrease the distance between the electrodes with each successive ratchet. Choudry, like Schmaltz, teaches that the “knob” is moved to the next ratchet or lock with increased pressure on the handles by the user; so, the prior art does not protect against the overexertion of pressure on the flange of the incision. Furthermore, Choudry teaches a locking release mechanism that requires more pressure be exerted upon the handles by the user so that the “knob” can move over the last ratchet or lock such that the “knob” essentially falls off the back of the last ratchet or lock and the handles are returned to the original position by a spring mechanism. Choudry’s disclosure is diametrically opposed to the teachings of the current application. Choudry’s locking release system is operated by increasing pressure on the handles resulting in the distance between the electrodes decreasing past the predetermined distance such that the electrodes will increase the pressure on the flange of the incision. The current invention teaches, however, that the adjustable stop means could comprise an adjustable knob. The same teachings and limitations apply to this stop mechanism in that the stop means prevents the overexertion of pressure upon the handles in order to decrease the risks of scarring and burning and to decrease healing time.

Also, the “knob” as disclosed by Choudry is completely different in both design and function than that disclosed by the current application. The Choudry “knob” moves over a system of a ratchets to hold the electrodes apart a desired distance. The knob as disclosed in the current application is described as “a knob 108 with recess 109 for the operator’s finger on the external side of the arm.” Application paragraph 124. The knob is in a strictly fixed location to allow for greater control of the instrument and contains a recessed spot for the operator’s fingers for greater ease in manipulation of the instrument. Application paragraph 124. The knob serves as a member of the stopping means regardless of whether the stopping means comprises a replaceable lug, one or more

spacers, or an electromagnetic means. Thus, the adjustable knob disclosed by the prior art and that of the current application are inherently distinct such that the 103(a) rejections to claims 68 and 74 should be withdrawn.

Conclusion

In view of the foregoing arguments, Applicant respectfully asks that all rejections be withdrawn and all claims be allowed. Believing that all things raised in the Examiner's August 23, 2005 Office Action have been addressed, the undersigned respectfully requests that the application be allowed and passed to issue.

Respectfully submitted,



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